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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/734,638	12/15/2003	Philippe Rouanet	029488-0113	9056

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EXAMINER	
COTTON, ABIGAIL MANDA	
ART UNIT	**PAPER NUMBER**
1617	

DATE MAILED: 10/02/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/734,638	ROUANET ET AL.	
	Examiner	Art Unit	
	Abigail M. Cotton	1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *07 August 2006 and 28 August 2006*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *26-28,31-36 and 38* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *26-28,31-36 and 38* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *8/28/2006*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

This office action is in response to the amendment and remarks submitted on August 7, 2006. Claims 26-28, 31-36 and 38 are pending in the application and are being examined on the merits herein.

The objection to claim 31 is being withdrawn in view of Applicant's amendment to correct the typo-type error.

The rejection of claims 26-27 under 35 U.S.C. 102(b) as being anticipated by U.S. Patent No. 5,904,930 to Fischer et al, the rejection of claims 26-27 under 35 U.S.C. 102(b) as being anticipated by the article to Sauvez as evidenced by Block, and the rejection of claims 26-29 under 35 U.S.C. 102(b) as being anticipated by U.S. Patent No. 4,919,937 to Mauvais-Jarvis et al. as evidenced by Block, are being withdrawn in view of Applicant's amendments to claim 26. In particular, the references do not teach a specific composition comprising 4-hydroxy tamoxifen and at least one fatty acid ester penetration enhancer, as required by newly amended claim 26, and thus do not anticipated claim 26 or the claims depending therefrom.

The rejections of the claims as set forth below have been required by Applicant's amendments.

Election/Restrictions

Applicant's affirmation, without traverse, of the election of the claims Group II in the response submitted August 7, 2006, is acknowledged.

The restriction requirement is deemed proper and is made final.

Oath/Declaration

The Examiner has previously indicated that the application papers do not give a post office address that was in effect at the time of filing of the oath or declaration for each of the inventors. The Examiner has respectfully requested that applicants provide a statement over each applicant's signature providing a complete post office address.

Applicants have indicated that they believe the complete post office address was properly submitted in the Declaration and Power of Attorney submitted on October 19, 2004. However, the Examiner notes that while the Declaration and Power of Attorney filed on October 19, 2004 appears to contain the *residence* of each of the applicants, it does not appear to provide their *post office address*. Appropriate correction is respectfully requested.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 26-28, 31-34 and 36 are rejected under 35 U.S.C. 103(a) as being obvious over U.S. Patent No. 4,919,937 to Mauvais-Jarvis et al, in view of DE 3836862 A1 to Gunther et al, published May 3, 1990.

Mauvais-Jarvis et al. teaches a precutaneously administrable drug of the hydroalcoholic type comprising 4-hydroxytamoxifen, and which can also comprise the steroid hormone progesterone (see abstract, column 2, lines 25-35 and column 3, lines 30-45, in particular.) Mauvais-Jarvis et al. further exemplifies a composition comprising progesterone, 4-hydroxytamoxifen, ethyl alcohol and water (see column 3, lines 30-45, in particular.) Mauvais-Jarvis et al. further teaches that the hydroalcoholic gel comprises various excipients required for enabling percutaneous penetration to take place (see column 3, lines 10-40, in particular.)

Mauvais-Jarvis et al. does not specifically teach that the composition comprises a fatty acid ester penetration enhancer, as recited in claims 26, such as isopropyl myristate, as recited in claim 31.

Gunther et al teaches a composition for transdermal administration of steroid hormones comprising a fatty acid ester (see abstract, in particular), as recited in claim 26. Gunther et al. teaches that fatty acid esters ensure adequate penetration of the active ingredient through the skin for therapy, and that a preferred fatty acid ester is isopropyl myristate (see specification, first page, in particular), as recited in claim 31.

Accordingly, one of ordinary skill in the art at the time the invention was made would have found it obvious to provide the isopropyl myristate of Gunther et al. in the percutaneous composition of Mauvais-Jarvis et al, because Mauvais-Jarvis et al. teaches that the composition comprising the 4-hydroxy tamoxifen and progesterone steroid composition comprises ingredients to enable percutaneous penetration, and Gunther et al. teaches that the isopropyl myristate ensures percutaneous administration of steroids. Thus, one of ordinary skill in the art would have been motivated to combine the isopropyl myristate into the composition of Mauvais-Jarvis et al, with the expectation of providing a percutaneous formulation that provides suitable penetration of the 4-hydroxy tamoxifen and progesterone composition. Accordingly, claim 26 is obvious over the teachings of Mauvais-Jarvis et al. in view of Gunther et al.

Regarding claim 27, Mauvais-Jarvis et al. teaches the hydroalcoholic gel as recited in the claim (see column 3, lines 29-55, in particular.)

Regarding claim 28, the Mauvais-Jarvis et al. exemplifies a composition comprising a hydroalcoholic composition comprising the 4-hydroxytamoxifen, an aqueous vehicle (water), an alcoholic vehicle (ethyl alcohol), and a gelling agent (Carbopol 934) (see column 3, lines 30-40, in particular), whereas Gunther et al. teaches providing the penetration enhancer, as discussed above. Accordingly, the combined teachings Mauvais-Jarvis et al. and Gunther et al render the claimed composition obvious.

Regarding claim 31, Mauvais-Jarvis et al. exemplifies a composition comprising 0.15 g (0.15%) of 4-hydroxy tamoxifen, 50 mL of 95% ethyl alcohol, a quantity of water, and 1 g (1%) of carbopol 934 (gelling agent) (see column 3, lines 30-40, in particular), and thus teaches a composition having amounts of ingredients (a) and (c)-(e) that are close to and/or overlap with the ranges recited in the claim. Furthermore, it is considered that one of ordinary skill in the art at the time the invention was made would have found it obvious to vary and/or optimize the amount of the components provided in the hydroalcoholic gel composition, according to the guidance provided by Mauvais-Jarvis et al, to provide a composition having desired properties. It is noted that "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." In re Aller, 220

F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955.) Regarding the amount of the isopropyl myristate provided, as recited in part (e) of claim 31 and 33, it is noted that Gunther et al. exemplifies compositions with 10% and 2% isopropyl myristate. Furthermore, it is considered that one of ordinary skill in the art at the time the invention was made would have found it obvious to vary and/or optimize the amount of the isopropyl myristate provided in the composition, according to the guidance provided by Mauvais-Jarvis et al. and Gunther et al, to provide a composition having desired properties. It is noted that "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." In re Aller, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955.)

Regarding claim 32, it is noted that Mauvais-Jarvis et al. exemplifies a composition comprising 4-hydroxy tamoxifen in an amount of 0.15g (0.15%), which is considered to meet the limitation of being "about" 0.5% by weight, as recited in the claim (see column 3, lines 10-40, in particular.) Gunther teaches that concentration of active ingredient of from 0.2 to 20 weight percent can be provided by utilizing the fatty acid ester penetration enhancers (see first page, in particular.) Furthermore, it is considered that one of ordinary skill in the art at the time the invention was made would have found it obvious to vary and/or optimize the amount of 4-hydroxy tamoxifen provided in the composition, according to the guidance provided by Mauvais-Jarvis and the penetration enhancement teachings of Gunther, to provide a composition having desired properties. It is noted that "[W]here the general conditions of a claim are disclosed in the prior art, it

is not inventive to discover the optimum or workable ranges by routine experimentation." In re Aller, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955.)

Regarding claim 34, Mauvais-Jarvis et al. exemplifies the composition comprising 95% ethyl alcohol in an amount of 50 ml (see column 3, lines 10-40, in particular), which is close to and/or overlaps with the amount as claimed. Regarding claim 36, Mauvais-Jarvis et al. teaches the composition having Carbopol 934 (gelling agent), a polyacrylic acid, in an amount of 1.5 g (1.5%) (see column 3, lines 10-40, in particular), which meets the limitation of the claim. Furthermore, it is considered that one of ordinary skill in the art at the time the invention was made would have found it obvious to vary and/or optimize the amount of ethyl alcohol and/or gelling agent provided in the composition, according to the guidance provided by Mauvais-Jarvis et al. and Gunther et al, to provide a composition having desired properties. It is noted that "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." In re Aller, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955.)

Claim 35 is rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 4,919,937 to Mauvais-Jarvis et al, issued April 24, 1990, in view of DE 3836862 A1 to Gunther et al, published May 3, 1990, as applied to claims 26-28, 31-34 and 36 above, and further in view of U.S. Patent No. 5,720,963 to Walter P. Smith, issued February 24, 1998.

Mauvais-Jarvis et al. in view of Gunther et al, are applied as discussed for claims 26-28, 31-34 and 36 above, and teach a hydroalcoholic gel composition for percutaneous administration comprising 4-hydroxy tamoxifen.

Mauvais-Jarvis et al. also exemplify a composition comprising an aqueous vehicle in an amount that is close to and/or overlaps with that recited in claim 35. Furthermore, it is considered that one of ordinary skill in the art at the time the invention was made would have found it obvious to vary and/or optimize the amount of the aqueous vehicle provided in the composition, according to the guidance provided by Mauvais et al. and Gunther et al, to provide a composition having desired properties. It is noted that "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." In re Aller, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955.)

The references do not specifically teach providing an aqueous vehicle that is a phosphate buffered solution, as recited in claim 35.

Smith teaches topically applied treatments for skin, which can comprise gels (see abstract, in particular.) Smith teaches that topical treatments can be pH adjusted to within a desired range and may be buffered with buffers such as

trimethylolaminomethan (tromethane) or phosphate buffer (see column 32, lines 20-30, in particular), as recited in claim 35.

Accordingly, one of ordinary skill in the art at the time the invention was made would have found it obvious to provide the buffers of Smith in the hydroalcoholic gel of Mauvais-Jarvis et al and Gunther et al, because Mauvais-Jarvis and Gunther et al teach the composition is applied percutaneously (topically), and Smith teaches the buffers can be provided to maintain a desired pH of the a topical composition. Thus, one of ordinary skill in the art would have been motivated to provide the buffers of Smith in the composition of Mauvais-Jarvis et al. and Gunther et al, with the expectation of maintaining suitable pH of the composition for topical application.

Claim 38 is rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 4,919,937 to Mauvais-Jarvis et al, issued April 24, 1990, in view of DE 3836862 A1 to Gunther et al, published May 3, 1990, as applied to claims 26-28, 31-34 and 36 above, and further in view of U.S. Patent No. 6,013,270 to Hargraves et al, issued January 11, 2000.

Mauvais-Jarvis et al. and Gunther et al, are applied as discussed for claims 26-28, 31-34 and 36 above, and teach a hydroalcoholic gel composition for percutaneous administration comprising 4-hydroxy tamoxifen.

The references do not specifically teach that the composition is packaged in a unit dose packet of a multiple dose container with a metered pump, as recited in claim 38.

Hargraves et al. teaches a skin care kit having a skin care composition contained within a dispenser (see abstract, in particular.) Hargraves et al. teaches that the dispenser can comprise a metered pump that an provide multiple doses and is suitable for dispensing skin care compositions such as for medical applications and body care applications (see column 14, line 45 through column 20, line 15, in particular.)

Accordingly, one of ordinary skill in the art at the time the invention was made would have found it obvious to provide the dispenser of Hargraves et al. to dispense the composition of Mauvais-Jarvis et al. and Gunther et al, because Mauvais et al. and Gunther et al. teach a medical composition for percutaneous application (topical application), and Hargraves et al. teaches the dispenser dispenses topical compositions, such as medical compositions. Thus, one of ordinary skill in the art would have been motivated to provide the dispenser for the composition of Mauvais-et al. and Gunther et al, with the expectation of providing a device suitable for the dispensing of the topical composition.

Response to Arguments

Applicant's arguments filed August 7, 2006 have been fully considered but they are not persuasive.

In particular, Applicants argue that one of ordinary skill in the art would not have been motivated to provide the isopropyl myristate of Gunther et al. in the percutaneous administration of Mauvais-Jarvis et al, because Gunther et al. teaches penetration enhancement of steroid hormones, but not 4-hydroxy tamoxifen. The Examiner notes that Mauvais-Jarvis et al. teaches a percutaneous composition that comprises 4-hydroxy tamoxifen and progesterone, a steroid hormone, as discussed above. Accordingly, it is considered that one of ordinary skill in the art the time the invention was made would have found it obvious to provide the penetration enhancer of Gunther et al. with the expectation of improving the percutaneous penetration and administration of the composition of Mauvais-Jarvis et al.

Conclusion

No claims are allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP

§ 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Abigail M. Cotton whose telephone number is (571) 272-8779. The examiner can normally be reached on 9:30-6:00, M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreenivasan Padmanabhan can be reached on (571) 272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

AMC

SREENI PADMANABHAN
SUPERVISORY PATENT EXAMINER